510(k) Summary
for Z-Medica, LLC
D2 Hemostatic Dressing

JUL 17 2014

K140757

1. SUBMITTER/510(K) HOLDER

Z-Medica, LLC
4 Fairfield Blvd.
Wallingford, CT 06492
Contact Person: Sheila K Wallin
Telephone: 203-294-0000 x 308

Date Prepared: March 24, 2014

2. DEVICE NAME

Proprietary Name:	D2 Hemostatic Dressing
Common/Usual Name:	Dressing, Wound, Drug
Classification:	Unclassified
Classification Name:	Dressing
Product Code:	FRO

3. PREDICATE DEVICE

- K103641 HemCon GuardaCare™ XR Surgical

4. DEVICE DESCRIPTION

The D2 Hemostatic Dressing is composed of kaolin (hemostatic agent) bound to a non-woven gauze (polyester-rayon substrate). D2 Hemostatic Dressing is provided in a sterile, intuitive, simple to use dressing format that conforms readily to the wound.

The proposed indications for use are substantially equivalent to the predicate device (HemCon GuardaCare™ XR Surgical K103641 cleared June 16, 2011, for surgical wounds and traumatic injuries). D2 Hemostatic Dressing is intended for use as a hemostatic dressing for the temporary control of severely bleeding wounds such as surgical wounds and traumatic injuries.

In vivo testing evaluated the efficacy of the D2 Hemostatic Dressing versus predicate (GuardaCare XR Surgical) to control bleeding in traumatic and surgical wounds. The data supports the effectiveness of D2 Hemostatic Dressing in achieving hemostasis in both traumatic and surgical wounds.

5. INTENDED USE

D2 Hemostatic Dressing is intended for use as a hemostatic dressing for the temporary control of severely bleeding wounds such as surgical wounds and traumatic injuries.

6. TECHNOLOGICAL CHARACTERISTICS AND SUBSTANTIAL EQUIVALENCE

The D2 Hemostatic Dressing is substantially equivalent to the predicate device (HemCon GuardaCare™ XR Surgical - K103641) in that it has the same intended use and instructions for use, and similar design (hemostatic agent bound to a nonwoven polyester/rayon substrate with an x-ray detectable thread). Data included in this submission demonstrate that the device is as safe and as effective as the legally marketed predicate, and none of the differences between the D2 Hemostatic Dressing and the predicate device raise different questions of safety and effectiveness than the predicate device.

The D2 Hemostatic Dressing and the predicate device are substantially equivalent in that they contain a hemostatic agent that functions to control bleeding. Their mechanisms of action are also similar: in D2 Hemostatic Dressing the hemostatic agent is kaolin, a mineral, which triggers an electrostatic interaction when in contact with blood to promote clotting. GuardaCare XR Surgical uses a different hemostatic agent, chitosan, which is a polymer that also works by electrostatic interaction to promote clotting. Although the hemostatic components of these two products are different, their mechanism of action and outcome is substantially equivalent.

Additionally, the D2 Hemostatic Dressing is similar to Z-Medica's legally marketed kaolin-based hemostatic dressings (QuikClot eX, also marketed as Combat Gauze - K072474 and QuikClot Hemostatic Dressing - K123387) in that it has the same hemostatic agent (kaolin), and similar design and processing. The only difference in the existing products and the D2 Hemostatic Dressings is that calcium alginate is used instead of glycerin to bind the kaolin to the nonwoven gauze substrate. Calcium alginate was chosen because it was found that calcium alginate binds kaolin effectively to the gauze resulting in a de minimis release.

The D2 Hemostatic Dressing is offered in several configurations ranging from 1" x 1" x 1 ply to 4" x 12ft x 2 ply, packed individually or as a multipack.

7. PERFORMANCE TESTING

Biocompatibility testing for the intended application of the D2 Hemostatic Dressing was performed in accordance with the International Standards Organization (ISO) 10993 Guidelines, FDA General Program Memorandum No. G95-1 and the Office of Device Evaluation (ODE) Bluebook Memorandum G95-1 "Use of ISO-10993 Biological Evaluation of Medical Devices Part 1: Evaluation and Testing". Per these guidance documents biological evaluation testing was categorized as limited contact duration, external communicating device, tissue/bone/dentin communicating.

See Appendix 15 for complete protocols and reports of the testing.

Test	Description	Conclusion
Cytotoxicity	L929 Neutral Red Uptake according to ISO 10993-5:2009, 'Biological Evaluation of Medical Devices, Part 5: Tests for In Vitro Cytotoxicity'	Non-cytotoxic
Irritation	ISO 10993-10:2010, 'Biological Evaluation of Medical Devices, Part 10; Tests for Irritation and Skin Sensitization'	Non-irritating
Sensitization	ISO 10993-10:2010, 'Biological Evaluation of Medical Devices, Part 10; Tests for Irritation and Skin Sensitization'	Non-sensitizing
Systemic Injection (intraperitoneal and intravenous injection)	ISO 10993-11:2006, 'Biological Evaluation of Medical Devices, Part 11: Tests for Systemic Toxicity'	Non-toxic
Genotoxicity	ISO 10993-3:2003, 'Biological evaluation of medical devices Part 3: Tests for genotoxicity, carcinogenicity and reproductive toxicity'	Non- mutagenic
Subcutaneous implantation	ISO 10993-6, 2007, Biological Evaluation of Medical Devices - Part 6: Tests for Local Effects After Implantation	Non-toxic

8. SAFETY AND EFFICACY

In vivo testing evaluated the efficacy of the D2 Hemostatic Dressing. The results of bench and safety testing indicated that the new device is as safe and as effective as the predicate device. The D2 Hemostatic Dressing and the predicate device have similar safety and performance results.

Protocols and test reports of the *in vivo* testing can be found in Section 19 of this submission.

Test	Description	Conclusion
Comparison Testing of D2 Hemostatic Dressing in Swine Model	DESCRIPTION: The hemostatic efficacy of the D2 Hemostatic Dressing was compared to legally marketed hemostatic dressings, QuikClot ex (K072474) and HemCon GuardaCare™ XR Surgical (K103641), when used to control bleeding in wounds such as superficial and subcutaneous injuries, injuries/	D2 Hemostatic Dressing is effective in controlling bleeding from

	lacerations to spleen, mesentery and liver. RESULT: The performance of D2 Hemostatic Dressing was similar to the predicate devices.	wounds
Comparison Testing of D2 Hemostatic Dressing in Swine Femoral Artery Punch Injury Model	DESCRIPTION: The efficacy of D2 hemostatic dressings in controlling bleeding in Yorkshire Swine femoral artery punch injury model in comparison with predicate dressings (GuardaCare®). RESULT: The performance of D2 Hemostatic Dressing was similar to the predicate devices.	D2 Hemostatic Dressing is effective in controlling bleeding from severe traumatic injury

9. CONCLUSION

Z-Medica believes that based on the indications for use, technological characteristics, and comparison to predicate device, the D2 Hemostatic Dressing has been shown to be substantially equivalent to the predicate and is safe and effective for its intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

July 17, 2014

Z-Medica, LLC
Ms. Sheila K. Wallin
Vice President of Clinical & U.S. Regulatory Affairs
4 Fairfield Boulevard
Wallingford, Connecticut 06492

Re: K140757
Trade/Device Name: D2 Hemostatic Dressing
Regulatory Class: Unclassified
Product Code: FRO
Dated: April 29, 2014
Received: May 1, 2014

Dear Ms. Wallin:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

David Krause -S

for Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K140757

Device Name

D2 Hemostatic Dressing

Indications for Use *(Describe)*

D2 Hemostatic Dressing is intended for use as a hemostatic dressing for the temporary control of severely bleeding wounds such as surgical wounds and traumatic injuries.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Jiyoung Dang -S

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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